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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,660	03/19/2001	Roman Efrain Vasquez Lipi	2119-109	9057

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,660

Applicant(s)

VASQUEZ LIPI, ROMAN EFRAIN

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,17,18 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,17,18 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Amendment filed on December 2, 2002. Claims 1, 2, 4-15, 17, 18, 22-27 are pending. Claim rejections as indicated in the previous Office action dated July 2, 2002, are withdrawn in view of the claim amendments made by applicant. New rejections are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-15, 17, 18, 22-24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-15, and 18 are rejected because the claim limitations are inconsistent with the scope of the base claim, claim 1. Claim 1, by reciting, "consisting essentially of", excludes all other components that materially affect the novelty of the composition therein. There is no evidence in the record that the addition of vitamins and specific selection of excipient such as petrolatum and stearic acid materially affect the basic and novel characteristics of the invention in claim 1. See MPEP § 2111.03. It is noted that applicant's disclosure indicates that the vitamins are inherently present in some of the oils recited in claim 1 by certain amount. However, claims 10-15 specifically recite certain amounts of vitamins be present in the composition in claim 1, which does not require particular weight amount of the oil components. The limitations in claims 10-15

may require further incorporation of the additional amount of vitamins, in which case could exceed the scope of claim 1.

Claims 4-15, 17, 18, 22-27 are incomplete as depending on a rejected base claim, claim 3.

For examination purposes, examiner assumes that claims 4-15, 17, 18, 22-27 depend on claim 1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 4-15, 17, 22, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slimak (US 6099866) in view of Soto (Derwent Acc. No. 1984-271531), Kaplan (US 5047232), and George (US 3431340).

Slimak teaches a composition comprising beeswax and oil, with or without water, useful for treating topical wounds including burns. See abstract. The reference specifically provides motivation to limit the ingredients to wax, oil, and water, due to possibility of allergic reactions. See col. 12, lines 37 – 43. The reference teaches that antibiotics may be added. See col. 13, lines 10 – 17. See instant claim 22.

Slimak teaches to combine the beeswax with plant oils and suggest that animal oil can be further added therein. See col. 12, lines 16 – 44. Almond, olive, sunflower, and mineral oils are disclosed. The reference further teaches that “an oil similar to the

plant source of the wax" is preferably used, which include sunflower and olive oils. Accordingly, a skilled artisan would have been motivated to select these oils to combine with the beeswax composition. It is well known in the art that sunflower contains vitamin E. See instant claim 8.

The Slimak reference teaches when water, the excipient in this case, is used, the volume ratio of wax:oil:water can range from 1:0.1:0 to 1:6:6 to produce a soft, easily applicable composition for topical application to the skin. See col. 10, lines 55 – 60. See instant claim 2. While the specific weight amount of the each of oil components are not taught as recited in the instant claim, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Slimak, examiner views that one having ordinary skill in the art would have discovered the optimum or workable weight amount of the ingredients by routine experimentation. The skilled artisan would have considered the cost of the ingredients or the rheology or spreadability of the final product, as suggested by Slimak. See col. 10, lines 55 – 60. See also In re Boesch, 205 U.S.P.Q. 215 (C.C.P.A. 198) (holding it is within the skill in the art to select optimal parameters, such as amount of ingredients, in a composition in order to achieve a beneficial effect).

Slimak teaches all of the recited oils but castor oil and cod liver oils. The reference fails to provide specific motivation to select the recited oils in the instant claims.

Soto teaches method of treating skin injuries by topically applying a composition comprising essentially of olive oil (100 parts) and beeswax (10 parts) as the principal ingredients. See abstract. The reference also teaches that one of more aromatic plant oils can be further incorporated therein.

Kaplan teaches that almond oil and castor oil are emollients well known to one having ordinary skill in the art. See col. 3, lines 66-67; col. 4, lines 34 – 3. Specific examples that these oils are used in mineral oil-based composition are shown in Examples 1, 2, 3, and 13. See instant claim 17. The examples also employ vitamin E in the weight amount of 0.1 -1 % by weight. See instant claim 9.

Slimak, Soto, and Kaplan fail to suggest combining castor oil, cod liver oil, and vitamins A and D with the beeswax composition in Slimak.

George teaches that castor oil and cod liver oil are well known for the treatment of burns. See col. 2, lines 1 – 61. The reference teaches a topical composition consisting essentially of 35-65 % by weight of castor oil and 35-65 % by weight of cod liver oil. The reference recites, “[t]he castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil, while at the same time promoting the healing of the wounds.” See col. 2, lines 45 – 48; see also col. 2, lines 15 – 26. The reference also teaches that cod liver oil contains at least 1000 USP units of vitamin A and 100 USP units of vitamin D per gram. See col. 2, lines 21 – 26. See instant claims 6-13. The reference further teaches that “[a]dditional quantities of vehicles, vitamins, and other fortifying substances may be as required.” See col. 2, lines 9-14.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings in the Slimak, Soto, and George references, the instant claims define the concomitant use of conventional therapeutic agents known for burn treatment. It would follow that the combination of beeswax, olive oil, castor oil, and cod liver oil and the method of use thereof is prima facie obvious.

Furthermore, given the general teaching in Slimak of burn treatment composition which essentially consist of beeswax, oil, and water, it would have been obvious to one having ordinary skill in the art at the time the invention was made to look for the prior arts such as Soto and George for specific types of oils beneficial and well known for burn treatment. Selecting almond oil from the disclosed oils in Slimak and combining it with the composition would have been also obvious, as the skilled artisan reading Kaplan would have been motivated to add an emollient component to improve skin condition.

2. Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slimak, Soto, Kaplan, and George as applied to claims 1, 2, 4-15, 17, 22, and 24-27 above, and further in view of Martin (US 5874479).

The combined references fail to teach stearic acid and BHT.

Martin teaches topical wound-healing compositions useful for, among others, healing of burns. See col. 23, lines 1 –9. Martin teaches that stearic acid is one of “the most common saturated fatty acids” required for the repair of cellular membranes and production of new cells. See col. 14, lines 21 – 64. See instant claim 18. The reference further teaches that BHT is an art-recognized preservative. See col. 13, lines 53-54. See instant claim 23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding well-known fatty acids such as stearic acid, as motivated by Martin, because of the expectation of successfully producing an enhanced wound-treatment composition which is effective in repairing cell membrane and producing new cells. The motivation to use a conventional preservative well known in pharmaceutical art such as BHT would have been also obvious to the routineer in view of Martin.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4-15, 17, 18, and 22-27 have been considered but are moot in view of the new ground(s) of rejection.

Declaration filed on December 2, 2002 has been fully considered, but applicants' arguments based on the submitted evidence are moot in view of the new grounds of rejection. While applicants assert that the present invention comprising essentially of beeswax, oleaginous base, and white petrolatum exhibits superior results than prior art containing active agents, as shown by the prior arts cited above, the ingredients used in

the present invention are themselves old and well known as therapeutic healing agents for burns.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

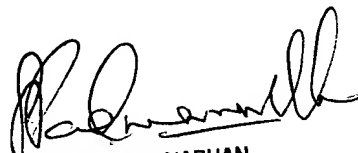
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
February 12, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

2/14/03